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§12–6C–03.2.

(a) Notwithstanding any other provision of this subtitle, a wholesale distributor applicant or permit holder that prepares sterile drug products shall submit to the Board a report of an inspection conducted by the U.S. Food and Drug Administration or a Board designee:

(1) At the time of application; and

(2) On renewal.

(b) The inspection report required under subsection (a) of this section shall:

(1) Be conducted within 1 year before the date of application or renewal; and

(2) Demonstrate compliance with applicable federal good manufacturing practice standards.

(c) An applicant or permit holder is responsible for obtaining an inspection to meet the requirements of this section.

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